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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,650	10/17/2003	Peter Nollert	018062-003130US	1247

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EXAMINER

GORDON, BRIAN R

ART UNIT	PAPER NUMBER
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1743

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No. 10/688,650	Applicant(s) NOLLERT ET AL.	
	Examiner Brian R. Gordon	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4-30-04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 50-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. Claims 50-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wallach US 5,147,723 and Safabash, 5,957,166.

Wallach discloses preparing lipid vesicles. The polyoxyethylene (2) cetyl ether, cholesterol and dicetyl phosphate were placed in a 5 ml syringe (first syringe) and heated to 40.degree. C., a temperature above the melting point of the lipid. The dicetyl phosphate provided a net negative charge to the final membrane structure. The lipophilic phase which resulted after the heating and blending of the lipophilic components was forcibly injected, via a three-way stopcock, into an aqueous phase consisting of 10 ml of 5 mM phosphate buffer containing 150 mM NaCl, pH 7.4. The phosphate buffer, which was contained in a 25 ml syringe (second syringe), was also at 40.degree. C. The process of injection of the lipophilic phase into the aqueous phase took less than five seconds. The resulting mixture was then forced into a second 25 ml syringe at a linear flow rate of 8-12 m/s through an orifice about 1 mm in diameter. The mixture was driven continuously back and forth between the two 25 ml syringes for approximately 2 minutes, providing the shear mixing necessary.

Wallach fails to disclose the lipid mixture is dispensed from the second syringe.

However Safabash discloses fluid dispersion and delivery assembly (16) includes first and second syringes (18,20) containing a first, fluid material (32) and a second material (34), fluidly coupled together at their distal ends (22,24) by a fluid transfer assembly (2). The fluid transfer assembly includes a double Luer fitting (4) and an

elongated, hollow, perforated tube (6) extending into the interior (26) of the second syringe. This permits the first, fluid material in the first syringe to be properly dispersed into the second material within the second syringe by simply pressing the plunger (28) of the first syringe. The sizing, spacing and positioning of the holes (14) in the tube can be adjusted to provide even or uneven fluid distribution within the second syringe. After dispersion, the fluid transfer assembly is dismounted from the second syringe to permit combined material (36) within the second syringe to be dispensed (abstract).

As to claims 51-54, it would have been obvious to one of ordinary skill in the art to recognize the material may be subsequently dispensed to any desired container, vessel, or plate for the purpose of further storing, further manipulation, testing, etc.

Conclusion

2. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kircher; Joseph J. et al.; Xu; Junquan et al.; Baker; Martin T. et al.; Yamazaki, Miki et al.; Chrislip; Mary Ann et al.; Unger; Evan C. et al.; Unger; Evan C. et al.; Henderson; Sheryl L. et al.; Freeman; Mary J. et al.; Popescu; Mircea C. et al.; and Bouma; Stanley R. et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, with 2nd and 4th F off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1743

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

brg

A handwritten signature in black ink, appearing to read 'BRG', followed by a long horizontal flourish.

BRIAN R. GORDON
PRIMARY EXAMINER